IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David C. Kulp et al.

Application No.: 10/063,559

Filed: May 2, 2002

For: Method, System, and Computer software for Providing a Genomic Web Portal

Examiner: Carolyn L. Smith

Art Unit: 1631

PETITION TO MAKE SPECIAL UNDER 37 CFR 1.102(d)

Commissioner for Patents
Alexandria, VA 22313-1450

The Assignee and Inventors of U.S. Patent Application Serial No. 10/063,559, hereby request that the present application be made special under the provisions described in MPEP 708.02 part VIII, SPECIAL EXAMINING PROCEDURE FOR CERTAIN NEW APPLICATIONS – ACCELERATED EXAMINATION.

We also enclose with this Petition the following papers that are required under 37 C.F.R. §1.102(d): A fee transmittal form authorizing the Commissioner to charge the $130.00 fee specified in 37 C.F.R. §1.17(h) for filing this Petition; a Statement that a pre-examination search was made with a copy of the PCT International Search Report; a copy of a Second Search Report performed by Matt Kasap, Inc.; and a Detailed Discussion that points out with particularity how the claimed subject matter is patentable over the references. Additionally, the following papers are being filed concurrently with this petition: A Preliminary Amendment that amends the claim of priority and includes an amended claim set; and A Second Supplemental Information Disclosure Statement and form 1449 that makes the references cited in the Second Search Report of official record in the present application.

The present paper contains the statement that a pre-examination search was conducted by the PCT search authorities and second pre-examination search was conducted by Matt Kasap, Inc., as well as the detailed discussion of the references.

If there are any other fees due in connection with the filing of this Petition, please charge the fees to Deposit Account 01-0431.

Remarks

Claims 19, 49-51, and 61-66 are pending in this case, assuming the admission of a preliminary amendment filed concurrently herewith, which the applicant believes are directed to a single invention. Claims 1-60 were originally filed and searched, claims 1-18, 20-48, and 52-60 are cancelled, and claims 61-66 are newly added via the amendment filed concurrently herewith. The applicants respectfully assert that the subject matter of the newly added claims are within the scope of the originally filed claims and are directed to a single invention.

In reference to the requirement to submit a search of the invention, the applicant respectfully submits that a pre-examination search was performed on March 26, 2003 in reference to a co-pending PCT application (attached), which is a foreign counterpart of the present application. The applicants are also submitting the results of a second, independent pre-examination search performed on September 30, 2003 by Matt Kasap Inc. Additionally the applicant submitted an information disclosure statement on May 29, 2002, a supplemental information disclosure statement on September 30, 2003, and a second supplemental information disclosure statement filed concurrently herewith, making all references cited in the PCT preliminary search report and second pre-examination search report of official record in the present application. The applicants also respectfully assert that the PCT international pre-examination search was directed to the invention defined in original claims 1-60, and the second Kasap pre-examination search was directed towards the following subject matter as described on the search report: "providing biological information such as probe sets identifying targets, collecting this information and analyzing it in a computer, and presenting to a user over a network as a graphical representation of the data". The applicants respectfully assert that the subject matter of the second pre-examination search is directed to the invention as claimed in pending claims 19, 49-51, and 61-66 assuming the admission of a preliminary amendment filed concurrently herewith.

PCT Pre-examination Search

The PCT search was directed towards original claims 1-60, and identified 5 references each of which were categorized as "Y" references and 3 were categorized as "X" references. Each of the references were cited and made of record on form 1449 filed September 30, 2003 and are discussed further below.

US 2001/0018642 A1 to Balaban et al., is a continuation of US Patent Application Serial No. 09/122,304 that has issued as US Patent Serial No. 6,188,783 B1 and has been submitted as citation number 2 on form 1449 of the original information disclosure statement. US 2001/0018642 A1 is also noted on the PCT search report and listed as citation number 1 on form 1449 of the supplemental information disclosure statement. US 2001/0018642 A1 teaches a system and method for organizing information relating to the design of probe arrays that includes a database model that organizes information interrelating probes on an array, genomic information investigated by the array and sequence information related to the design of the array. Additionally, a network for interconnecting multiple computer systems such as a local or wide area network is described.

The embodiments described US 2001/0018642 A1 fail to teach a method or system for providing information related to probe sets to a user in response to a user selection of one or more probe set identifiers. Further, the embodiments described in US 2001/0018642 A1 do not teach the correlation of a first set of data associated with the user selection of one or more user selected probe set identifiers with a second set of data. Specifically, US 2001/0018642 A1 does not teach providing a user with a second set of data in response to a user selection of one or more probe set identifiers.

Reese (2000) is noted on the PCT search report and listed as citation number 2 on form 1449 of the supplemental information disclosure statement. Reese (2000) teaches a hidden markov model based system for gene prediction or gene-finding. Three embodiments are described that include a system based upon statistical properties of coding genes, a system includes EST alignment information, and a system that integrates protein sequence homology information. Reese (2000) further teaches biological sequence information used for training the hidden markov models and for gene prediction analysis.

Wagner (1997) is noted on the PCT search report and listed as citation number 3 on form 1449 of the supplemental information disclosure statement. Wagner (1997) teaches a statistical method for identifying clusters of DNA binding sites in a genomic sequence that are unlikely to occur by chance alone. Wagner (1997) further teaches the identification of genes likely to be regulated by a transcription factor using additional information that includes biochemical

function of the transcription factor, structure of the binding site, and the function of genes near the cluster.

Claverie (1998) is noted on the PCT search report and listed as citation number 5 on form 1449 of the supplemental information disclosure statement. Claverie (1998) teaches computational methods that identify exons in anonymous genomic sequences. Claverie (1998) further teaches that the methods may be performed locally or remotely and may use sequence information provided by a variety of databases.

Cuff (2000) is noted on the PCT search report and listed as citation number 4 on form 1449 of the supplemental information disclosure statement. Cuff (2000) teaches a procedure for building multiple sequence alignments using information available from EST sequences. More specifically, Cuff (2000) teaches the use of embodiments of the well known BLAST algorithm for clustering and aligning biological sequences from the EMBL-EST database based upon the sequence similarity.

The embodiments described in Reese (2000), Wagner (1997), Claverie (1998), and Cuff (2000) references each fail to teach probe set identifiers that identify probe sets capable of identifying biological molecules. Further, the embodiments of each of the references fail to teach a first set of data associated with the one or more probe set identifiers correlated to a second set of data.

Second Pre-examination Search

As discussed above, the applicants respectfully assert that pending claims 19, 49-51, and 61-66 were subject to a separate search by Matt Kasap, Inc. Each of the references cited in the second pre-examination search are made of record on form 1449 filed concurrently herewith. Also, each of the references has been reviewed and a discussion of each of the relevant references is included below.

Some references cited on the second pre-examination search report are not discussed here and the applicants respectfully assert that each of the references has no bearing upon the patentability of the pending claims. The references generally teach bioinformatic methods and

systems for analyzing data produced by biological probe arrays, and database systems and/or structures for data storage. Also, a number of the references do not have an earliest effective priority date that pre-dates the May 3, 2001 priority date of the present application.

US 2003/0125315 A1 to Mjalli et al. is listed as citation number 29 on form 1449 of the second supplemental information disclosure statement and teaches a system and method for drug discovery that matches the structure of one or more molecular "probes" with binding sites on pharmacological targets. Additionally, Mjalli et al. teaches a user workstation that accesses a web server that generates a user interface, such as a graphical user interface, that accepts parameters and presents results of molecular association between the probe molecule and the pharmacological target. The web server is also enabled to access a variety of local or remote databases.

The embodiments described in Mjalli et al. fail to teach receiving a first set of one or more probe set identifiers. More specifically, Mjalli et al. does not teach a probe set identifier associated with a set of one or more probes from an array of probes on a microarray as described in paragraph 56, lines 1-2 of the present application. Further Mjalli et al. fails to teach that the probe set as described above is capable of the identification of a biological molecule. Additionally, Mjalli et al. fails to teach the correlation of the first set of one or more probe set identifiers with a first set of data that is further correlated with a second set of one or more data that is provided to the user.

US 2003/0009296 A1 to Sabatini et al. is listed as citation number 18 on form 1449 of the second supplemental information disclosure statement and teaches systems and methods for providing sequences of biological molecules in a relational database format that is accessible in a client-server environment. The sequences are generally provided in response to a set of one or more input sequences that are compared against one or more libraries or databases of sequence information using the well known BLAST and other similar sequence alignment algorithms. Sabatini et al. also teaches a graphical user interface that includes a comparative genomics user interface that allows the user to compare the sequence data of sets of different organism types.

The embodiments described in Sabatini et al. fail to teach receiving a set of one or more probe-set identifiers that identify a probe-set capable of the identification of a biological molecule. In particular, Sabatini et al. does not describe a probe set identifier associated with a set of one or more probes from an array of probes on a microarray as described in paragraph 56, lines 1-2 of the present application. Additionally, Sabatini et al. fails to teach correlating a first set of one or more probe set identifiers with a first set of one or more data that is then correlated with a second set of one or more data that is provided to the user.

US 2002/0187464 A1 to Klempner et al. is listed as citation 17 on form 1449 of the second supplemental information disclosure statement and teaches systems and methods of identifying receptors and biological constructs using biological arrays with what are generally referred to as phages that display one type of affinity ligand reagent (ALR) disposed thereupon. Also, Klempner et al. describes providing information concerning biological construct or receptor ALR binding patterns to a first computer through a second computer, where a computer includes a web server and the first and second computers may be connected by a network and the information is compared to records in a database and a list of matching information is compiled.

The embodiments described in Klempner et al. fail to teach receiving a user selection of a first set of one or more probe set identifiers that are correlated with a first set of one or more data, where each probe set identifier identifies one or more probes of a probe set. Also, US Klempner et al. fails to teach correlating the first set of one or more data with a second set of one or more data that is provided to the user. Specifically, Klempner et al. does not describe correlating the first set of one or more data, such as the list of matching information, with a second set of one or more data as described in paragraph 87, lines 1-3 of the present application.

US 2003/0054394 A1 to Chin et al. et al. is listed as citation 21 on form 1449 of the second supplemental information disclosure statement and teaches systems and methods for identifying candidate genes from a plurality of DNA sequences using homology searches such as the well known BLAST algorithm. Additionally, Chin et al. teaches client systems and a server system enabled to communicate over a network, such as the internet, where the server system receives information requests from the client systems and processes the requests and forwards the results back to the client systems. The server also obtains annotation information associated

with the DNA sequences and their corresponding homologs that is summarized and stored in a database. Moreover, Chin et al. teaches obtaining and storing expression profile data in a database associated with genes and their homologs, such as that obtained for experiments with probe arrays. The above mentioned database may be queried using criteria characterizing candidate genes such as by gene classification or attribute similarity.

The embodiments described in Chin et al. fail to teach receiving a first set of one or more probe-set identifiers that each identifies a probe-set capable of identifying a biological molecule. More specifically, Chin et al. does not teach a probe set identifier associated with a set of one or more probes from an array of probes on a microarray as described in paragraph 56, lines 1-2 of the present application. Further, Chin et al. fails to teach providing a second set of one or more data to a user in response to a first set of one or more probe set identifiers as described above, where the response is based upon a correlation of the first set of probe-set identifiers with a first set of one or more data, and a correlation of the first set of one or more data with a second set of one or more data.

References filed in Information Disclosure Statement Form 1449

The following references were not cited in either search report, but were cited and submitted on form 1449 of one of the information disclosure submissions and are discussed below.

Some references were cited on form 1449 but are not specifically discussed here because the applicants respectfully assert that each of the references simply shows general background for the pending claims. The references generally teach database structures, interfaces for sequence comparison and/or analysis where most are enabled to employ one or more remote databases, or probe array design and manufacture. Also, the above mentioned references each fail to teach correlating a first set of data with a second set data based, at least in part, upon one or more associated probe set identifiers.

US 5,630,125 to Zellweger is listed as citation number 1 on form 1449 of the information disclosure statement filed on May 29, 2002, and teaches an Application Generator, the Distribution files generated by the Application Generator, and a Retrieval system which accesses the Distribution files. The Retrieval system uses data in the Distribution files to configure an

Information System which runs stand-alone on a desktop computer. The Information system uses an "Open Hierarchical Data Structure" for classifying information objects and providing a menu access to them that may, in one embodiment, be applied to manage and distribute product information to buyers in the form of an "electronic catalog". The described embodiments include the Retrieval system and Distribution files generated by the Application Generator, being delivered to the user in the form of computer media which is described to include CD-ROM and floppy disks that are then installed and run on the user's computer hard drive. The Retrieval system then creates the Information system on said hard drive using the data stored in the Distribution files. One embodiment teaches the storage of the Distribution files on a remote computer where the Retrieval module running on the user computer queries the Distribution files via a network.

The embodiments described in Zellweger fail to teach correlating a first set of data with a second set of data based upon a first set of probe set identifiers. Additionally, Zellweger does not teach providing a user with the second set of data associated with the first set of one or more probe set identifiers or probe set identifiers that identify probe sets capable of identifying biological molecules.

EP 1 043 667 A2 to Saischek, is listed as citation number 5 on form 1449 of the information disclosure statement filed on May 29, 2002, but only the basic abstract was available to the applicant in English at the time of filing. The applicants subsequently had the reference translated into English which the applicants believe is a true and accurate translation of the original reference that is respectfully submitted as citation number 39 on form 1449 of the second supplemental information disclosure statement filed concurrently herewith.

Saischek teaches an online service accessed via the internet that supports a number of databases containing chemical product information that further includes a process system that communicates with the providers of chemical products enabling the vendors to register, store, alter, and delete product and contact information. The described service is also enabled to generate a quotation to send to a purchaser.

The embodiments described in the Saischek fails to teach correlating a first set of data with a second set data based, at least in part, upon one or more associated probe set identifiers. Further, Saischek fails to teach probe set identifiers that identify probe sets capable of identifying biological molecules, and in particular Saischek fails to teach a probe set identifier associated with a set of one or more probes from an array of probes on a microarray as described in paragraph 56, lines 1-2 of the present application.

WO 00/70556 to Ren et al. is listed as citation number 9 on form 1449 of the information disclosure statement filed on May 29, 2002, and teaches a method and system for analyzing data over a network that receives genomic information obtained from hybridized probe array data and performs an analysis of samples based upon a user selection. Further, Ren et al. teaches client systems that communicate with a web server where a user can upload and store genomic information, such as information obtained from experiments with probe arrays, in a database associated with the web server and interactively perform analysis of the information. Additionally, Ren et al. teaches that the result of the analysis is a list or a list of lists of genes that can be stored in a database and/or compared to one or more other lists, where the lists or related information may be retrieved from the database via the web server.

The embodiments described in Ren et al. fails to teach providing a second set of one or more data to a user in response to a first set of one or more probe set identifiers, where the response is based upon a correlation of the first set of probe-set identifiers with a first set of one or more data, and a correlation of the first set of one or more data with a second set of one or more data.

6,180,351 B1 to Cattell is listed as citation number 1 on form 1449 of the second supplemental information disclosure statement filed concurrently herewith, and teaches a method and system for generating an addressable array of biopolymers, such as DNA probes, based upon an array layout and an associated first identifier received from a remote station. The term array layout is defined in column 6, line 64 as:

> "one or more characteristics of the array, such as feature positioning, feature size, and some indication of a moiety at a given location"

The associated first identifier corresponds to the unique identifier described in column 10, line 53, the format of which is described in US Patent serial No. 5,812,793 to the Microsoft Corporation that generally teaches unique identifiers for data transmitted over a network or internet.

2002/0120183 A1 to Abraham-Fuchs et al. is listed as citation number 11 on form 1449 of the second supplemental information disclosure statement filed concurrently herewith, and teaches a method and a network for evaluating medical data using biochips tested with patient samples in a number of test devices used at the particular point of care site. Abraham-Fuchs et al. further teaches in paragraph 22, line 4:

> "The raw point of care data obtained as a result of this measurement are transmitted to the remote server, particularly to a data evaluation expert system at, or accessible by, the remote server. The expert system applies expert rules to obtain an evaluation result(diagnosis) in step 6, with the diagnosis result transmitted back to the point of care site"

2002/0091490 A1 to Russo et al. is listed as citation number 9 on form 1449 of the second supplemental information disclosure statement filed concurrently herewith, and teaches a system for representing and manipulating biological data using a biological object model, that in some embodiments may be accessible via a network or internet. Russo et al. further teaches in paragraph 56, line 1:

> "First, a database engine, such as database engine 210, receives (910) a request for biological data. Next, a database engine, such as database engine 210, searches (920) a database, such as database 240, for the requested biological data. After the requested biological data is located in the database, the database engine retrieves (930) the biological data. Next, a data-mapping engine, such as data-mapping engine 230, determines (940) the format of the retrieved biological data."

The embodiments described in the Cattell, Abraham-Fuchs et al., and Russo et al. references each fail to teach correlating a first set of data with a second set of data based upon a first set of probe set identifiers. Further, each of the references fails to teach providing a user with the second set of data associated with one or more probe set identifiers or probe set identifiers that identify probe sets capable of identifying biological molecules.

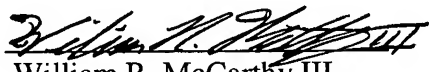
Applicants believe the application is now in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at 408-731-5021.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 01-0431.

If the Examiner has any questions pertaining to this application, the Examiner is requested to contact the undersigned attorney.

Respectfully submitted,

Date: February 27, 2004



William R. McCarthy III
Reg. No. P-55,788

Customer No. 22886
Affymetrix, Inc.
3380 Central Expressway
Santa Clara, CA 95051
Phone (781) 280-1522
Fax (781) 687-9090